UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of **Scheduling 4-OH-DiPT, 5-MeO-AMT, 5-MeO-MiPT, 5-MeO-DET, and DiPT**	**Docket No. 22-15** ADMINISTRATIVE LAW JUDGE TERESA A. WALLBAUM

JASON WALLACH AND HAMILTON MORRIS' AMENDED SUPPLEMENTAL PREHEARING STATEMENT

John T. Hunter
Attorney
Hunter, Lane & Jampala
310 S. St. Mary's Street
Suite 1740-Tower Life Bldg.
San Antonio, Texas 78205
(210) 202-1076
(210) 880-6162 (*telecopier*)
John@HLJDefense.com

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Pursuant to the Administrative Law Judge's February 1, 2022 Order for Prehearing Statements and Second Order Modifying Order for Prehearing Statements, the Jason Wallach and Hamilton Morris hereby submit their Supplemental Prehearing Statement in the above- captioned matter.

This amended filing of what was submitted on July 7, 2022, includes only the identifying information and testimonial summary of one additional witness, Terry A. Dal Cason, whose availability to testify is contingent upon the issuance of a subpoena by this Honorable Court.

ISSUES

1. Whether N,N-Diisopropyltryptamine (DiPT) should be listed in Schedule I of the Controlled Substances Act, pursuant to 21 U.S.C. §§ 811 & 812(b)(1).

REQUESTED RELIEF

Jason Wallach and Hamilton Morris request that the Tribunal recommend that DiPT should not be listed in Schedule I of the Controlled Substances Act, pursuant to 21 U.S.C. §§ 811 & 812(b)(1).

PROPOSED WITNESSES

1. Nicholas Denomme
   Department of Pharmacology
   University of Michigan Medical School
   2301 MSRB III
   110 W. Medical Center Dr.
   Ann Arbor, Michigan 48109
   ndenomme@umich.edu

2. Jason Wallach Ph.D.*
   Saint Joseph's University
   600 South 43rd Street
   Philadelphia, PA 19104

3. Hamilton Morris*
   Saint Joseph's University
   600 South 43rd Street
   Philadelphia, PA 19104

4. Jeffery Becker M.D.
   1614 State Street
   Santa Barbra, CA 93101
   jeffrey@bexsonbiomedical.com

5. Adam Halberstadt Ph.D.
   9500 Gilman Dr.
   La Jolla, CA 92093

6. Terry Dal Cason
   8644 Sunshine Lane
   Orland Park, Illinois 60462**

*Hamilton Morris and Jason Wallach are represented as interested parties in this matter. Please forward all correspondence for Mr. Morris and Dr. Wallach to *John@hljdefense.com*.

**Terry Dal Cason will not testify without the issuance of a subpoena. For this reason, he was not included in the original prehearing statement, and this Amended Supplemental Prehearing Statement is being submitted to provide notice of what is anticipated to be elicited from the witness only if a subpoena issues for his appearance.

SUMMARY OF TESTIMONY

1. Nicholas Denomme

Nicholas Denomme will testify that he is currently a pharmacologist and a Ph.D. candidate at the University of Michigan. His academic focus is on the neuropharmacology of hallucinogenic drugs, which he has studied for the past ten years. He qualifies as an expert in the field of neuropharmacology. He will testify to and authenticate learned treatises of several scientific publications concerning the chemistry, neuropharmacology, and psychology that have critical bearing on the question of DiPT's safety, medical potential, mechanism of action, and abuse potential : (1) (Shulgin & Carter, 1980); (2) (Shulgin and Shulgin, 1997); (3) (Shulgin, 1988); (4) (Shergill et al., 1998); (5) (Holmes and Tinnin, 1995); (6) (Brewin and Patel, 2010).

He will testify that, while DiPT is a tryptamine, and thus molecularly similar to many hallucinogenic drugs, it manifests markedly different effects on the human body. In particular, DiPT is unique in that it primarily precipitates a wide spectrum of auditory distortions, a feature that suggest and that the research strongly indicates, enables it to bind to receptors in the body that act to process and understand auditory

information.

He will further testify that the way the brain receives and processes auditory information in poorly understood in the medical and scientific community. Despite the overwhelming persistence of auditory hallucination in diseases such as schizophrenia and post-traumatic stress disorder, the currently accepted psychiatric protocols and pharmacological interventions are failing to adequately address these symptoms for many patients (Holmes and Tinnin, 1995, Shergill et al., 1998, Brewin and Patel., 2010, Blom. 2015, Moore et al., 2019, Grundfast and Jamil, 2022, Brewin and Patel. 2010, Blom for many patients (Holmes and Tinnin, 1995, Shergill et al., 1998, Brewin and Patel., 2010, Blom. 2015, Moore et al., 2019, Grundfast and Jamil, 2022). The current pharmacological research conducted by Mr. Denomme in coordination with Dr. Wallach and Mr. Morris is attempting to determine the mechanisms and effects of electrical excitability on the neurons in the inner ear and/or auditory cortex using DiPT.

He will further testify that the decision to place DiPT in Schedule 1 will have significant negative impacts on the continuation of his research. From the financial, supply chain, and collaborative perspectives, a Schedule 1 designation creates enough of an economic disincentive for academics to continue to fund and support critical research. It especially makes studies that attempt to ascertain the most relevant molecular structures of the drug costly and difficult, as any resulting modifications of the molecule used to test the functions of the molecular structure necessarily must begin from the Scheduled molecule itself. Due to this characteristic of the molecule, Scheduling DiPT would create a significant roadblock to advancing scientific

knowledge.

2. <u>Jason Wallach Ph.D.</u>

Dr. Wallach will testify that he is currently an assistant professor at St. Joseph's University with a Ph.D. in Pharmacology and Toxicology. He has over 15 years' experience studying psychoactive drugs including psychoactive tryptamines. He qualifies as an expert in the fields of analytical chemistry, organic synthesis, medicinal chemistry, pharmacology and toxicology. In addition to his work in academia he serves as a consultant and/or leads drug development projects for several pharmaceutical companies around psychoactive drug development. He has been studying DiPT for over 10 years as an auditory distorting compound; this includes structure activity relationship studies, pharmacological target elucidation, and exploring potential novel therapeutic applications.

He will testify to and authenticate as learned treatises several scientific publications concerning the chemistry and neuropharmacology, and psychology that have critical bearing on the question of DiPT's safety, medical potential, mechanism of action, and abuse potential : (1) (Shulgin & Carter, 1980); (2) (Shulgin and Shulgin, 1997); (Shulgin. 1988); (Blough et al. 2014); (Halberstadt et al. 2020); (Hamlet 2010); (Ray. 2010); (Sexton et al. 2020); (Mallaroni et al. 2022).

He will testify that, while DiPT is a tryptamine, and thus molecularly similar to the neurotransmitter serotonin and many hallucinogenic drugs, it manifests markedly different effects on the human body. In particular, DiPT is unique in that at common

dosages it primarily precipitates a spectrum of auditory distortions, features that suggest, and that the research strongly indicates, that it binds to previously unknown receptors in the body that act to detect, process and/or understand auditory information. He will testify that the reported effects are distinct from schedule I hallucinogens ((Shulgin & Carter, 1980); (2) (Shulgin and Shulgin, 1997); Shulgin. 1988); (Liechti et al. 2017); (Vollenweider et al. (2007). He will testify that despite over a decade of research we still do not understand how this molecule uniquely acts to distort auditory perception. He will testify as to the scientific and potential medical value such an understanding may have.

He will further testify that his review of the academic and medical literature fails to reveal a single documented report of DiPT's misuse or abuse, nor its role in any adverse medical outcomes. He will testify that recent studies on use prevalence suggest extreme rarity of self-reported DiPT use among the general public and psychoactive drug users (Sexton et al. 2020); (Mallaroni et al. 2022). He will testify that he conducted a recent search of the website www.drugsdata.org, the website of an anonymous forensic drug analysis program where individuals submit samples for analytical testing. Searching using keywords "DiPT" and "DIPT" turned up 55 entries spanning from 2001 to 2022. The majority (50 entries) of submissions, which were comprised of pressed tablets, capsules and powders were in reference to and/or were discovered to contain the schedule I hallucinogen 5-MeO-DiPT. In fact, not a single submission was found to contain DiPT. One entry from 2015 was comprised of a powder of "supposed DiPT" was found to contain 5-MeO-MiPT with the submitter stating "Unsure what it is but effects

are not right for DiPT." While anecdotal this demonstrates what the learned treatises provided (Shulgin and Carter. 1980, Shulgin et al. 1986), support, that this user was anticipating a subjective effect from DiPT distinct in nature from that of a hallucinogenic tryptamine.

Dr. Wallach will testify that his time studying the molecule has not revealed any instances of DiPT's diversion from legitimate channels to be used recreationally; that it does not pose any potential public health risks; and that the drug's potential for recreational use or abuse is extremely unlikely.

He will testify that given what is known about its effects the actual potential for abuse is negligible. The drug is not currently abused with any frequency and is not commonly available to the public**.** Its known effects on auditory perception are not sufficiently desirable to create a market for the substance in the same fashion as we have seen for other tryptamine hallucinogens. There is no evidence that the effects impair judgement or would lead to dangerous behavior; extensive literature searches of google scholar and pubmed fail to turn up any reports of adverse reaction to DiPT and no such reports are provided by the government. The overwhelming majority of the substance that is bought and sold in legitimate channels funnels into research institutions for the purpose of conducting precisely the kind of medical research Mr. Denomme, Dr. Wallach, and Mr. Morris are conducting. Additionally, it would be practically impossible to chemically convert DiPT to any other currently known drug of abuse.

He will further testify that he knows of only a few if any documented cases in the

literature where individuals have taken this substance on their own initiative rather than based on medical advice. Given the nature of the drug and its pharmacological effects, it would be unlikely that the general public would encounter DiPT or seek it out – the amount of personal research and inquiry required to even appreciate what the substance is and what its pharmacological effects are, is self-limiting in its potential to be consumed in a haphazard fashion. Additionally, while DiPT is structurally related to other, popularly used tryptamine hallucinogens, its unique activity sets it sufficiently apart from such other drugs as to make abuse-potential comparisons impractical. He will testify that there is a lack of clear human data demonstrating hallucinogenic actions and that existing animal models to assess hallucinogen-like activity (e.g., drug discrimination and head twitch response), which have been used with DiPT, can lead to false positives (Fiorella et al. 1995); (Glennon and Hauck 1985); (White and Appel 1982); (Baker et al. 1997); (Goodwin et al. 2003); (Halberstadt et al. 2020).

Dr. Wallach will testify his research has uncovered DiPT may have medical utility in the treatment of disorders as diverse as tinnitus, auditory hallucinations, PTSD, schizophrenia, pain, and certain cancers. Dr. Wallach will testify as to and authenticate as learned treatises several scientific publications concerning the negative impact of scheduling on medical and scientific progress (Nutt et al. 2013a); (Nutt et al. 2013b); (Stewart and Kalueff. 2013). He will further testify that the decision to place DiPT in Schedule 1 will have significant negative impacts on the continuation of his research. From the financial, supply chain, and collaborative perspectives, a Schedule 1 designation creates enough of a disincentive for academics and contract research

organizations (CROs) to continue to fund and support critical research. Often research involves synthesis of the molecule of interest in a radioactive form in small quantities (less than 1 mg). This is typically done by CRO laboratories with specialized expertise in radiochemistry. Such small quantities would be treated restrictively and could require specialized licenses which limits the number of CROs that can comply. Scheduling makes studies that attempt to ascertain the most relevant molecular structures of the drug costly and difficult, as many resulting modifications of the molecule used to test the functions of the molecular structure necessarily must begin from the Scheduled molecule itself.

3. Hamilton Morris

Mr. Morris will testify that he is a journalist, documentarian, and medicinal chemist working at Saint Joseph's University in Philadelphia. Mr. Morris has been studying the history, chemistry and pharmacology of DiPT with Dr. Wallach for 13 years. During this time they have synthesized and pharmacologically evaluated a number of DiPT structural analogs with the hope of identifying DiPT's mechanism of action. He qualifies as an expert in the field of chemistry, and will further testify as a fact witness to provide a summary of the medical and scientific literature presently known on the subject of DiPT.

He will testify to and authenticate learned treatises of several scientific publications on the history, and pharmacology of DiPT. He will testify as to the history of DiPT, its unique qualitative effects compared to hallucinogenic tryptamines ((1) (Shulgin & Carter, 1980); (2) (Shulgin and Shulgin, 1997); (Shulgin. 1988), and the

extreme rarity of its use by humans (Sexton et al. 2020); Mallaroni et al. 2022). He will testify that the research of Dr. Wallach and himself has preliminarily indicated that DiPT may have medical utility in the treatment of disorders as diverse as tinnitus, auditory hallucinations, PTSD, schizophrenia, pain, and certain cancers.

Mr. Morris will testify about the difficulty of studying compounds like DiPT and how placement of DiPT in schedule I will interfere with research. He will testify as to the existence of learned treatises of several scientific publications concerning the negative impact of scheduling on scientific and medical progress (Nutt et al. 2013a); (Nutt et al. 2013b); (Stewart and Kalueff. 2013). Furthermore, Mr. Morris has conducted an extensive analysis of published work on DiPT in both scientific and journalistic literature and has concluded that there is no evidence to support the idea that DiPT is associated with dependence, abuse, or diversion. Mr. Morris will testify to the fact that anonymous, unconfirmed, anecdotal reports on the internet do not represent evidence of use, abuse, addiction, or diversion and call into question the idea that such reports should be used as the basis of scheduling decisions.

4. <u>Jeffrey Becker M.D.</u>

Jeffrey Becker, M.D. will testify that he is a clinical psychiatrist and Chief Scientific Officer of Bexson Biomedical, a pharmaceutical development company focused on non-opioid solutions to chronic pain and novel approaches to PTSD, Treatment Resistant Depression, Opioid Addiction and Suicide. Dr. Becker has four years of experience overseeing drug development projects involving CSA scheduled compounds including multiple schedule I drugs. He qualifies as an expert in

the fields of medicine and clinical psychiatry.

He will offer testimony regarding the time-sensitive nature of the early drug development process and how this issue is impacted by CSA scheduling of a compound. He will testify as to the impact Schedule I status has upon the cost of research and the availability of academic laboratories or contract research organizations (CROs) to collaborate with towards solving serious medical issues plaguing American civilians and military service members. Dr. Becker will testify as to and authenticate as learned treatises several scientific publications concerning the negative impact of scheduling on medical and scientific progress (Nutt et al. 2013a); (Nutt et al. 2013b); (Stewart and Kalueff. 2013).

He will discuss how the cost and difficulty of sourcing schedule I substances, specifically in relation to other scheduled drugs (e.g., schedule II-III), has directly slowed development in this space through cost and supply chain friction. He will testify regarding how schedule I status impacts decisions on where to focus resources and efforts in a manner that is independent from scientific evidence.

5. <u>Adam Halberstadt Ph.D.</u>

Adam Halberstadt will testify that he has a Ph.D. in neurobiology. He has over 15 years of experience studying psychoactive drugs with a focus on rodent psychopharmacology and behavioral testing. He has done extensive work studying the mechanism of action of serotonergic hallucinogens. He has also investigated DiPT. Dr. Halberstadt qualifies as an expert in the field of neurobiology, as well as an expert on rodent psychopharmacology and behavioral testing, including the interpretation of such

studies.

Dr. Halberstadt will testify to and authenticate learned treatises and several scientific publications concerning the pharmacology of known hallucinogens, he will also testify to the receptor level and behavioral neuropharmacology that have critical bearing on the question of DiPT's safety, medical potential, mechanism of action, and abuse potential. (Holze et al. 2020; Liechti et al. 2017; Vollenweider et al. 2007, Syder et al. 1971, Szara et al. 1966).

Dr. Halberstadt will testify that no incidents or published case reports were cited in the scheduling justification to demonstrate that users have actually been harmed by DIPT. Reference was made to one DIPT user who described problems with their hearing, but there is no indication they were evaluated by a medical professional and there is no way to link the symptoms to the use of DIPT (King-Kopetzky syndrome can occur spontaneously). So, with the exception of a poorly documented user report mentioning King-Kopetzky syndrome, all of the harms listed for DIPT are predictions based on the known risks of Schedule 1 hallucinogens. The risks listed for DIPT in the scheduling justification are the same risks that would be predicted for any drug that mimics the effects of LSD, psilocybin, and other Schedule 1 hallucinogens.

Dr. Halberstadt will review risks associated with the use of Schedule I hallucinogens for non-medical purposes (Carbonaro et al. 2016); (Johnson et al. 2008); (Griffiths et al. 2006); (Holze et al. 2021); (Eisner and Cohen 1958); (Zeifman et al. 2021); (Strassman 1984).

He will testify that the risks predicted for DIPT in the government's documents are based on the expectation that it produces the same set of effects in humans as LSD and other Schedule I hallucinogens. The overall logic in the scheduling justification seems to be that Schedule I hallucinogens are hazardous for users, and DIPT produces "hallucinogenic" effects, so therefore DIPT will also be hazardous for users. But DIPT does not really mimic the subjective effects produced by Schedule I hallucinogens. DIPT primarily affects auditory perception and has little or no effect on cognition, mood, or other sensory modalities. There is no reason to predict that distortions of auditory perception, where perceived pitch is downshifted, would result in confusion, disorientation, or dangerous behavior. He has reviewed numerous online experience reports written by DIPT users and while some individuals found the auditory distortion to be annoying or tiresome, in no cases did they become fearful or panic because of the effect. In the absence of major shifts in mood, cognition, and visual perception, there is no reason to expect that altered pitch perception would cause people to behave erratically, act in ways that would expose themselves or others to danger, or would precipitate depressive or psychotic episodes. Additional data must be collected to understand how individuals will react to drugs that alter pitch perception. Nevertheless, the published case reports about carbamazepine contain relevant data. Although some of the carbamazepine patients were frustrated by the auditory distortion and had difficulty playing musical instruments, as far as he is aware, none of the patients became fearful or displayed erratic or dangerous behavior (Chaloupka et al. 1994); (Braun and Chaloupka. 2005). Without further data, therefore, he does not believe any definitive predictions can be made regarding the likely risks associated with

the unsupervised use of DIPT. But based on its subjective effects, there is not a good rationale to predict that DIPT would have the same risks as Schedule I hallucinogens.

He will testify that DiPT has a unique subjective pharmacology in humans as an auditory distorting compound, which is distinct from hallucinogenic tryptamines **(**1) (Shulgin & Carter, 1980); (2) (Shulgin and Shulgin, 1997); Shulgin. 1988); and that such unique effects have yet to be demonstrated in rodent models (Halberstadt et al. 2020); (Carbonaro et al. 2013); (Carbonaro et al. 2015); (Gatch et al. 2011); (Smith et al. 2014).

He will testify that given the unique pharmacology of DiPT as an auditory distorting compound it is highly unlikely to be used in a manner consistent with other scheduled tryptamine hallucinogens

He will testify as to the role of 5-HT2A in mediating the subjective effects of hallucinogens like LSD and Psilocybin (Halberstadt 2015); (Nichols 2016); (Holze et al. 2021); (Madsen et al. 2019).

He will testify that although activation of the 5-HT2A receptor can induce hallucinogenic effects in humans, not all 5-HT2A agonists act as hallucinogens. For example, lisuride, a close structural analog of LSD, acts as a 5-HT2A agonist but does not produce hallucinogenic effects in humans (Herrmann et al. 1977); (Verde et al. 1980). Lisuride has even been used as a medication and has efficacy against various

disorders, including migraine (Herrmann et al. 1977); and Parkinson's disease (Lieberman et al. 1983).

According to in vitro studies, DIPT binds to the 5-HT2A receptor and acts as a 5-HT2A agonist (Blough et al. 2014; Carbonaro et al. 2015; Rickli et al. 2016). Nevertheless, given what is known about the activity of lisuride in humans, the in vitro data with DIPT must be interpreted cautiously; even though DIPT acts as a 5-HT2A agonist, it cannot be assumed that DIPT will produce LSD-like hallucinogenic effects in humans via 5-HT2A activation.

As noted in the scheduling justification, DIPT has been tested in drug discrimination studies performed in rats. The drug discrimination paradigm is used to classify drugs based on their perceived interoceptive stimulus effects. Typically, in drug discrimination studies, rats are trained to press one of two levers after they receive a training drug, and must press the other lever after they receive saline. Once animals can reliably discriminate between the two training conditions, challenge experiments can be conducted with other drugs to evaluate whether their effects are perceived as being similar to the cue produced by the training drug. Drugs that cause the animals to respond primarily on the drug lever are said to fully substitute for the stimulus properties of the training drug.

When tested in drug discrimination studies, DIPT produced full substitution in rats trained to discriminate the Schedule I hallucinogen DOM (Gatch et al. 2011; Glennon

et al. 1983). DIPT also produced full substitution in rats trained to discriminate the Schedule I hallucinogen DMT (Gatch et al. 2011). Rats have been trained to discriminate DIPT from saline; LSD and DOM fully substituted in DIPT-trained rats, whereas DMT only partially substituted and (+)-methamphetamine failed to substitute. Based on those findings, there appears to be considerable overlap between the stimulus effects produced by DIPT and the Schedule I hallucinogens LSD, DOM, and DMT.

Note however that drug discrimination assesses the pharmacological similarities between drugs but does not model their subjective effects in humans. Drug discrimination studies are susceptible to false positives (a drug that produce full substitution even though it does not mimic the subjective effects produced by the training drug in humans).

Fenfluramine, a Schedule III anorexic drug, is an example of a drug that can act as a false positive in drug discrimination studies. Rats trained to discriminate the Schedule I drug MDMA from saline will fully generalize to fenfluramine (Baker et al. 1997; Goodwin et al. 2003). MDMA is the prototypical member of the entactogen drug class (Nichols 1986; Nichols et al. 1986); in humans, MDMA produces euphoria, feelings of empathy and closeness to others, and stimulation. Fenfluramine by contrast, does not produce MDMA-like effects in humans, and actually induces feelings of dysphoria at higher doses (Foltin and Fischman 1991; Griffith et al. 1975). Hence, fenfluramine can be viewed as an MDMA false-positive in drug discrimination studies.

Lisuride is another drug that can act as a false positive in drug discrimination. According to multiple drug discrimination studies in rats, both the LSD stimulus and

the DOM stimulus will fully generalize to lisuride (Fiorella et al. 1995; Glennon and Hauck 1985; White and Appel 1982). Obviously, lisuride does not mimic the subjective effects produced by LSD and DOM in humans.

Given the activity of fenfluramine and lisuride, data from drug discrimination studies must be interpreted cautiously. Because certain drugs can act as false positives in drug discrimination, when there is a conflict between drug discrimination data and empirical human data, the findings in humans must take precedence. In the case of DIPT, there is a discrepancy between its activity in the drug discrimination paradigm vs. its subjective effects in humans. DIPT mimics the stimulus effects of schedule I hallucinogens in rats, but does not mimic the subjective effects produced by Schedule I hallucinogens in humans. Given that situation, more weight must be given to the human data. I can think of a few potential explanations for these seemingly incongruous data. First, it should be noted that it is not clear to what extent the subjective effects produced by DIPT are mediated by the 5-HT2A receptor. Because DIPT does not seem to mimic the typical effects produced by 5-HT2A agonistssuch as LSD in humans, the auditory distortions induced by DIPT may not be mediated by 5-HT2A. DIPT and other N,N-dialkyltryptamines bind promiscuously to a large range of monoaminergic receptors and transporters (Blough et al. 2014; Rickli et al. 2016); one of those other monoaminergic sites may mediate the auditory distortion induced by DIPT, or the effect could be mediated by some other, yet uncharacterized site. Given those facts, there are three potential explanations for the activity of DIPT:

(1) A non-5-HT2A site mediates the auditory distortion produced by DIPT. DIPT is also a hallucinogenic 5-HT2A agonist, but only occupies the 5-HT2A receptor to a limited extent when administered at dosage levels that induce auditory distortion.

(2) A non-5-HT2A site mediates the auditory distortion produced by DIPT. DIPT also acts as a nonhallucinogenic 5-HT2A agonist (similar to lisuride), so although DIPT activates 5-HT2A when taken at dosage levels that induce auditory distortion, the effect on 5-HT2A does not provoke LSD-like hallucinogenic effects in humans.

(3) DIPT acts as a 5-HT2A agonist in humans, but the way the effect is expressed subjectively is qualitatively different compared to LSD and other hallucinogenic 5-HT2A agonists.

Without further testing and data, there is no way to rule out those three potential explanations.

He will further testify that his review of the academic and medical literature fails to reveal a single documented report of DiPT's misuse or abuse, nor its role in any adverse medical outcomes; that it does not pose any potential public health risks; and that the drug's potential for recreational abuse is extremely unlikely.

Dr. Halberstadt will also testify that the analysis provided in the scheduling justification is very superficial and contains errors. Given the limited anecdotal data available for DIPT, it appears there are considerable qualitative differences between the effects produced by DIPT in humans compared to Schedule 1 hallucinogens such as

LSD and psilocybin. DIPT appears to produce a unique drug effect in humans. Because of those differences, there is no reason to expect that the recreational use of DIPT will necessarily have the same health risks and dangers as the unsupervised use of Schedule 1 hallucinogens. In addition, although DIPT clearly acts as a 5-HT_{2A} receptor agonist, it is not clear that those receptor interactions are actually responsible for mediating the subjective effects produced by DIPT in humans. Additional data are required to clarify the exact nature of the effects that DIPT produces in humans, the mechanism for those effects, and what risks are associated with the use of DIPT. He will testify that, at the present time, it is his judgement that sufficient evidence does not exist to support the conclusion that DIPT has the same effects or risks in humans as Schedule I hallucinogens.

6. Terry A. Dal Cason

Terry Dal Cason has reviewed the STRIDE and NFLIS literature pertaining to factors 4 and 5 of the 8 factor analysis submitted against DiPT, and can attest to that data's insufficiency to establish either that a pattern for abuse of this substance exists or that any current or past instances of abuse are significant enough to justify the scheduling decision at issue in this case. This testimony is essential, especially in light of the Government's concession that its designated witnesses are not prepared to testify about the law enforcement data underpinning factors 4 and 5 of the analysis, and in light of this Court's order denying the Parties' requests for disclosure regarding this underlying data. It is further anticipated that Mr. Dal Cason can attest that structural similarity of DiPT to other scheduled compounds, without regard to the similarity of pharmacological effects. While no formal legal conclusions would be elicited from the

witness – acknowledging that this Court is the final arbiter of the law – Terry Dal Cason's practical experience working for the DEA and describing how aberrant abuse or diversions of an unscheduled substance can be lodged and proved under the Analog statute of 1986 would meaningfully assist the trier of fact.

It is anticipated that Terry Dal Cason can be certified as an expert in the field of chemistry. It is also anticipated that his training and experience with the DEA as a chemist who has testified on behalf of the DEA in clandestine drug manufacturing cases would also assist the trier of fact in a field of detailed and specialized knowledge which would also fall under the purview of Federal Rule of Evidence 702.

EXHIBITS

(1) Shulgin, Alexander T. and Michael F. Carter. "N,N-Diisopropyltryptamine (DIPT) and 5-Methoxy-N,N-Diisopropyltryptamine (5-MEO-DIPT). Two Orally Active Tryptamine Analogs with CNS Activity." Communications in Psychopharmacology 4, 1980 (7 pages)

(2) Shulgin A and Shulgin A (1997). TIHKAL. The Continuation. Transform Press. Edited by D Joy. (2 pages)

(3) Thomas P, Mathur P, Gottesman II, Nagpal R, Nimgaonkar VL and Deshpande SN (2007). Correlates of hallucinations in schizophrenia: A cross-cultural evaluation. Schizophrenia Research 92:41-49 (9 pages)

(4) Holmes DS and Tinnin LW (1995). The problem of auditory hallucinations in combat PTSD. Traumatology. (7 pages)

(5) Brewin CR and Patel T (2010). Auditory pseudohallucinations in United Kingdom war veterans and civilians with posttraumatic stress disorder. Journal of Clinical Psychiatry 71: 419–425. (6 pages)

(6) González JC, Aguilar EJ, Berenguer V, Leal C and Sanjuan J (2006). Persistent auditory hallucinations. Psychopathology 39:120–125. (6 pages)

(7) Halberstadt, A.L., Chatha, M., Klein, A.K., Wallach, J. and Brandt, S.D., 2020. Correlation between the potency of hallucinogens in the mouse head-twitch response assay and their behavioral and subjective effects in other species. *Neuropharmacology*, *167*, p.107933. (12 pages)

(8) Gatch, M.B., Hoch, A. and Carbonaro, T.M., 2020. Discriminative Stimulus Effects of Substituted Tryptamines in Rats. *ACS pharmacology & translational science*, *4*(2), pp.467-471. (4 pages).

(9) Carbonaro, T.M., Eshleman, A.J., Forster, M.J., Cheng, K., Rice, K.C. and Gatch, M.B., 2015. The role of 5-HT2A, 5-HT2C and mGlu2 receptors in the behavioral effects of tryptamine hallucinogens N, N-dimethyltryptamine and N, N-diisopropyltryptamine in rats and mice. *Psychopharmacology*, *232*(1), pp.275-284. (9 pages)

(10) Carbonaro, T.M., Forster, M.J. and Gatch, M.B., 2013. Discriminative stimulus effects of N, N-diisopropyltryptamine. *Psychopharmacology*, *226*(2), pp.241-246. (6 pages)

The following supplemental exhibits are also offered, in response to the Government's production in the case, each classified by the witness who will be testifying about the exhibit:

Nick Denomme:

Blom, J.D., 2015. Auditory hallucinations. *Handbook of clinical neurology*, *129*, pp.433-455. (23 pages)

Brewin CR and Patel T (2010). Auditory pseudohallucinations in United Kingdom war veterans and civilians with posttraumatic stress disorder. Journal of Clinical Psychiatry 71: 419–425. (6 pages)

Grundfast, K.M. and Jamil, T.L., 2022. Evaluation and Management of Tinnitus: Are There Opportunities for Improvement?. *Otolaryngology–Head and Neck Surgery*, p.01945998221088286. (14 pages).

Holmes DS and Tinnin LW (1995). The problem of auditory hallucinations in combat PTSD. Traumatology. (7 pages)

Moore, B.A., Moring, J.C., Hale, W.J. and Peterson, A.L., 2019. Incidence rates of tinnitus in active duty military service members between 2001 and 2015. *American Journal of Audiology*, *28*(4), pp.866-876. (11 pages).

Shergill SS, Murray RM, McGuire PK. Auditory hallucinations: a review of

psychological treatments. *Schizophrenia Research*, 1998;32(3):137-150. (14 pages).

Shulgin A. DiPT: The Distortion of Music. High Frontiers/Reality Hackers. Jan 1, 1988. (1 page).

Shulgin A and Shulgin A (1997). TIHKAL. The Continuation. Transform Press. Edited by D
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OTHER MATTERS

The supplemental exhibits have been served electronically on the DEA contemporaneous with the submission of this prehearing statement. Hard copies of all materials cited in this statement have been shipped in hard-copy form to this Honorable Court.

ESTIMATE OF TIME

Wallach and Morris estimate that they can present their case-in-chief in one day, exclusive of cross-examination and rebuttal.

Dated: July 7, 2022

Respectfully submitted,

/s/ John T. Hunter

John T. Hunter
Attorney

Hunter, Lane & Jampala
310 S. St. Mary's Street
Suite 1740-Tower Life Bldg.
San Antonio, Texas 78205
(210) 202-1076
(210) 880-6162 (*telecopier*)
John@HLJDefense.com

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2022, I electronically submitted the foregoing to the DEA Office of the Administrative Law Judges via the DEA Judicial Mailbox, at ECF-DEA@dea.gov, DEA.Registration.Litigation@dea.gov and simultaneously to the Government and fellow Objectors at:

- David Locher and Andrew Winler, attorneys for the DEA, at David.M.Locher@dea.gov and Andrew.T.Winkler@dea.gov
- Matthew C. Zorn, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at mzorn@yettercoleman.com;
- Graham Pechenik, Esq., Counsel for Tactogen Inc. and Mindstate Design Labs, via email at graham@calyxlaw.com;
- David Heldreth, CEO of Panacea Plant Sciences, via email at davidh@panaceaplantsciences.net; and

/s/ John T. Hunter
John T. Hunter